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1992 FEB 4

SPECIAL PROGRAM **EXAMINATION UNIT**

Ronald L. Wilson, Director Health Assessment Policy Staff Office of Health Affairs (HFY-20) Food and Drug Administration 5600 Fisher's Lane, Room 11-44 Rockville, MD 20857

Re: Dermatop FDA Docket No. 91E-0476

Dear Mr. Wilson:

Transmitted herewith is a copy of the application for patent term extension of U.S. Patent No. 4,242,334 issued December 30, 1980. The application was filed on November 12, 1991, under Title II of Public Law 98 - 417, the Drug Price Competition and Patent Term Restoration Act of 1984.

The patent claims a product that was subject to regulatory review under the Federal Food, Drug and Cosmetic Act. Subject to final review, the subject patent is considered to be eligible for patent term restoration. Thus, a determination by your office on the applicable regulatory review period is necessary. Accordingly, notice and a copy of the application are provided pursuant to 35 USC § 156 (d) (2) (A).

Charles E. Van Horn

Patent Policy & Programs Administrator

C.E.Van Hom

Office of the Assistant Commissioner for Patents

Tatsuya Ikeda cc:

Hoechst Celanese Corp., Patent Dept. Route 202-206, P.O. Box 2500 Somerville, NJ 08876-1258